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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/591,307	06/09/2000	David A. Edwards	2685.2001-000	2060

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EXAMINER
HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
1616	15

DATE MAILED: 05/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/591,307	EDWARDS ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11 & 14* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-45, 47 and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maa et al (6,284,282).

Maa teaches methods of preparing a dry powder composition comprising spray freeze-drying an aqueous mixture of a protein under conditions to provide a respirable dry powder. Maa also teaches methods of administering a therapeutically effective dose of a therapeutic protein to a patient comprising administering to the alveolar regions of the lungs of the patient a spray freeze dried therapeutic protein dry powder composition (col. 2, lines 28-55).

The term "powder" is described as a composition that consists of finely dispersed solid particles that are relatively free flowing and capable of being readily dispersed in an inhalation device and subsequently inhaled by a patient so that the particles can reach the alveoli of the lung. Thus, the powder is respirable and suitable for pulmonary delivery. The average particle size ranges from about 5 μm to about 30 μm. the preferred average particle size is 6-8 μm. The FPF, fine powder fraction, is preferably at least 10%, and especially preferred at 40 to 50%. The particles have a tap density of less than about 0.8 g/cm^3, with tap densities of less than about 0.4 g/cm^3 being

preferred and less than about 0.1 g/cm^3 being especially preferred (see col. 5, line 30 to col. 6, line 33).

Maa discloses suitable proteins for the said preparation in column 6, which include insulin, antibodies and growth hormone. The protein particles are able to penetrate into the alveolar regions of the lungs pf the patient. The powders are formulated into unit dosages comprising therapeutically effective amounts of therapeutic proteins. A unit dosage means a receptacle containing a therapeutically effective amount of a spray freeze dried therapeutic protein. The unit dosage containers may be associated with inhalers that will deliver the powder to the patient. These inhalers may optionally have chambers into which the powder is dispersed, suitable for inhalation by a patient (col. 12, line 53 to col. 13, line 30).

Although Maa does not specifically disclose the mass of particles delivered, it clearly teaches powders dispersed from the dose chamber of the inhalation device (col. 17, lines 47 to col. 18, line 36). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the teachings of Maa et al by concentrating on more specific volume of receptacle and mass of particles delivered because knowing the specific values regarding dosages in treating certain disorders is very important and helpful to the health care providers and patients. Furthermore, it would have been obvious to a routineer in the art to have modified the method of Maa by substituting the proteins with other active agents by routine experimentation and to broaden the scope of therapy.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/878,146. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter in both sets of claims is the same.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The amendments to claim 1 overcame the Double patenting rejection of claims 1-3, 8-9 and 18-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. patent No. 6,136,295. Thus, this rejection is withdrawn.

Response to Arguments

Applicant's arguments filed 03/17/03 have been fully considered but they are not persuasive.

Applicant argues that Maa et al fail to teach or suggest all of the claim limitations because "while Maa et al generically teach such criteria, the Examples section of heir specification teaches that the dispersion measurements of their particulate powders were calculated using a 10:1 (lactose carrier:powder) blend. This is not persuasive because 1) as the applicant stated the disclosure of lactose is in the examples. If Maa et al had exemplified the composition as required by the instant claims the appropriate rejection would have been a 102 rejection. 2)the text of specification of Maa et al clearly teaches that excipients (such as lactose) are optional additives and that they are preferably used in small amounts of less than 2-3% (col. 8, lines 23 and 44-50). 3) it is noted that the claims are given the broadest interpretation during examination and that references are evaluated by what they suggest to one versed in the art, rather than by specific disclosures. *In re* Bozek, 163 U.S.P.Q. 545 (CCPA 1969). The instant claims cite "a composition comprising.....", which is an open language and does not exclude excipients. Thus it is shown that Maa et al, is clearly teaching all the limitations.

Applicant also argues that "Maa et al do not teach or suggest a method of delivering a therapeutic dose of a bioactive agent to the pulmonary system, in a single breath, wherein at least about 50% of the mass of particles stored in the receptacle is delivered to the pulmonary system of the subject". This is not persuasive because it is concluded that when the components of a composition or a method are met by the prior

art, even if some properties are not specifically disclosed by the prior art, they are ultimately met. In this instant, when Maa et al disclose method of delivery of spray dried particles, meeting the tap density and fine particle fractions of the instant claims, there is no indication that at least 50% of the mass of particles stored in the receptacle is not delivered to the pulmonary system of the subject.

Applicant argues that Maa et al do not disclose a method of delivering therapeutic dose of a bioactive agent to the pulmonary system of a subject, in a single breath, where at least 5 milligrams of the bioactive agent is delivered to the pulmonary system. This is not persuasive because the instant claims do not claim any specific bioactive agent, and there is no basis for comparison with prior art. Also noted that Maa et al disclose a wide range of proteins for the said composition and it is concluded that one or more of the said bioactive agents would deliver more than 5 milligrams to the pulmonary system of the subject.

Applicant argues that Maa et al fail to provide requisite reasonable expectation of success, because "in view of the teachings of Maa et al that the desired physical, aerodynamic and flow properties of their powder are due to the presence of large lactose carrier particles, the person of ordinary skill in the art would not have had a reasonable expectations of success". Again, this is not persuasive because as shown above, Maa et al teach that excipients such as lactose are preferably not used or used in very small quantities. In fact Maa et al disclose that "while the pre-spray freeze dry formulations utilizing little or no excipient may not be highly stable, the dry powders

made from these formulations can, for certain proteins, be both surprisingly stable and highly dispersible, as shown in the examples" (col. 9, lines 2-6).

Information Disclosure Statement

The listing of references on page 3 of the IDS is not a generally considered proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list **may not be** incorporated but must be submitted in a **separate paper**." Although these pages are signed and copies are enclosed, it would be helpful to examination procedure if all documents were listed on PTO-1449.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 703-308-6330. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghighatian
May 5, 2003

MICHAEL G. HARTLEY
PRIMARY EXAMINER